IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, LLC, FOREST LABORATORIES HOLDINGS, LTD., and ALLERGAN PHARMACEUTICALS INTERNATIONAL LTD., Plaintiffs,))) Civ. No. 14-1119- MSG) CONSOLIDATED
v. $ \begin{tabular}{ll} SIGMAPHARM LABORATORIES, LLC, \it{et} \\ \it{al.}, \\ \it{Defendants}. \end{tabular} $))))))

MEMORANDUM ORDER

On November 15, 2018, after a three-day bench trial, I issued a memorandum opinion and order (the "Trial Order") finding that an Abbreviated New Drug Application ("ANDA") filed by defendant Sigmapharm Laboratories, LLC ("Sigmapharm") literally infringed U.S. Patent Nos. 5,763,476 ("the '476 patent"). (D.I. 409; D.I. 410). The '476 patent is assigned to plaintiffs Forest Laboratories LLC, Forest Laboratories Holdings, Ltd., and Allergan Pharmaceuticals International Ltd. (collectively, "Forest"). The Trial Order stated that "[t]he parties shall submit an agreed upon form of final judgment to this effect." (D.I. 410).

At trial, Forest asserted that Sigmapharm infringed the '476 patent both literally and under the doctrine of equivalents. (D.I. 396 at 20-28; D.I. 401 at 8-15). Sigmapharm asserted a defense of prosecution history estoppel. (D.I. 401 at 8-15). Because I found that Sigmapharm's accused product literally infringed the '476 patent, I did not address the parties' arguments regarding the doctrine of equivalents and prosecution history estoppel.

Instead of submitting a proposed form of final judgment, Sigmapharm adopted, and the FDA apparently approved by default, an amendment to its ANDA intended to design around the '476 patent. (D.I. 411 at 3; D.I. 411-1). Sigmapharm cites to Federal Circuit precedent holding that "an amended ANDA that addresses the issue of infringement and precludes such infringement is generally dispositive." *Ferring B.V. v. Watson Labs., Inc.*, 764 F.3d 1382, 1391 (Fed. Cir. 2014). *Ferring B.V.* also states that it is within the discretion of the district court, "guided by principles of fairness and prejudice to the patent-holder," to reconsider a finding of infringement in light of an amended ANDA. *Id.* Thus, according to Sigmapharm it is not *per se* prejudicial that the amended ANDA was adopted after a post-trial finding of infringement. *See id.* at 1391-92 (affirming a lower court's decision that a post-trial amended ANDA precluded infringement).

Currently pending before me are: (i) Sigmapharm's motion for reconsideration of the Trial Order based on the amended ANDA pursuant to Fed. R. Civ. P. 60(b) (D.I. 411); (ii) Forest's motion for an extension of time to file a response to the motion for reconsideration (D.I. 412); and (iii) Forest's motion for entry of a final judgment pursuant to Fed. R. Civ. P. 54(b) (D.I. 413). Sigmapharm does not oppose Forest's request for an extension of time but does ask that the two substantive motions—the motion for reconsideration and motion for entry of a final judgement—be considered together. (D.I. 414). Sigmapharm further requests that the court grant oral argument on the two substantive motions. (*Id.*).

NOW, this 6th day of December, 2018, it is HEREBY ORDERED that:

- 1. Plaintiffs' Motion for an Extension of Time (D.I. 412) is GRANTED;
- 2. Plaintiffs' Response to the Motion for Reconsideration shall be filed on or before December 21, 2018;

- 3. Defendant's Reply to the Motion for Reconsideration shall be filed on or before January 4, 2019; and
- 4. Oral argument will be held on the Motion for Reconsideration (D.I. 411) and the Motion for Entry of Judgment (D.I. 413) at 2:00 p.m. on January 23, 2019 in Courtroom 4B at the United States Courthouse in Philadelphia, Pennsylvania.

/s/ Mitchell S. Goldberg
UNITED STATES DISTRICT HIDGE